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JUN 17 2004


Marina Velentgas Schneller
VENABLE
1201 New York Ave. NW Suite 1000
Washington DC 20005-3917

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,565,447

Dear Ms. Schneller:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,565,447 for a period of 569 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the PSC Forms Download Website:
<http://forms.psc.gov/forms/FDA/fda.html> (<http://forms.psc.gov/forms/FDA/Fda-3542.pdf>).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: AXERT (almotriptan malate)
FDA Docket No.: 02E-0019

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(12)

CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,565,447
(45) ISSUED : October 15, 1996
(75) INVENTOR : Dolores F. Forner, et al.
(73) PATENT OWNER : Almirall Prodesfarma, S.A.
(95) PRODUCT : AXERT® (almotriptan malate)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,565,447 based upon the regulatory review of the product AXERT® (almotriptan malate) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94)

569 days

from October 15, 2013, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 8th day of June 2004.

Jon W. Dudas

Jon W. Dudas
Acting Under Secretary of Commerce for
Intellectual Property and Acting Director of the
United States Patent and Trademark Office